

### REMARKS

This Application has been carefully reviewed in light of the Final Office Action mailed January 13, 2009. At the time of the Final Office Action, Claims 1-15, 19 and 20 were pending in this Application. Claims 1-10 were previously withdrawn due to an election/restriction requirement and Claims 16-18 were previously cancelled without prejudice or disclaimer. Claims 11-15, 19 and 20 stand rejected. Claims 11-15 and 19-20 have been amended. Applicant respectfully requests reconsideration and favorable action in this case.

#### **Rejections under 35 U.S.C. § 112, second paragraph (indefiniteness)**

Claims 11-15, 19 and 20 were rejected by the Examiner under 35 U.S.C. §112, second paragraph, as allegedly being indefinite due to the phrase “wherein the forming the suspension and dispersing steps occur after, but within hours of the initial formation of the area of skin lacking normal, healthy skin.” According to the Examiner, “after, but within hours” is essentially an infinite time period. The Examiner also alleges that the phrase “area of skin lacking normal, healthy skin” is indefinite, as well as the timing of the “initial formation” of an area of skin lacking normal, healthy skin. (Office Action, page 2).

Although Applicant does not necessarily agree with these rejections, Applicant has amended Claim 11 to recite “wherein the forming the suspension and dispersing steps occur after, but within one day of the formation of the wound area.” Support for both the “within one day” limitation and “formation of the wound area” limitation is found, e.g., at page 10, lines 6-9, which states “In one embodiment the autologous cells may be transplanted back to the patient within hours to days following the formation of a wound by a variety of mechanisms.” This word “hours” in the phrase “hours to days” clearly refers to a period of hours that is less than one day. Applicant further submits that the term “formation of the wound area” is sufficiently clear to one of ordinary skill in the art.

Therefore, Applicant respectfully request that the Examiner withdraw the rejection under 35 U.S.C. §112, second paragraph.

**Rejections under 35 U.S.C. § 112, first paragraph (written description)**

Claims 11-15, 19 and 20 were rejected by the Examiner under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, based on the phrase in Claim 11 “forming a suspension consisting of a subject’s isolated autologous stem cells and a soluble medium.” In particular, it appears that the Examiner’s position is that Applicant’s specification does not support a suspension that *consists only of* a subject’s isolated autologous stem cells and a soluble medium. Applicant has amended Claim 11 to recite “forming a suspension including a subject’s isolated autologous stem cells in a soluble medium.” A suspension including a subject’s isolated autologous stem cells in a soluble medium is clearly supported by the specification, and thus is not new matter.

Therefore, Applicant respectfully request that the Examiner withdraw the rejection under 35 U.S.C. §112, first paragraph.

**Rejections under 35 U.S.C. §103**

Claims 11-15, 19 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,479,052 issued to Julian M. Marshall et al. (“*Marshall*”) or “Aerosolization of Epiderman Cells with Fibrin Glue for the Epithelialization of Porcine Wounds with Unfavorable Topography,” *Plastic Surgery and the Cryopreservation Laboratory*, by Meir Cohen et al. (“*Cohen*”) and U.S. Patent No. 6,497,875 issued to J. Michael Sorrell et al. (“*Sorrell*”).

In order to establish a prima facie case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Even if each limitation is disclosed in a combination of references, however, a claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int’l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). Rather, the Examiner must identify an apparent reason to combine the known elements in the fashion claimed. *Id.* “Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must

be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.*, citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Finally, the reason must be free of the distortion caused by hindsight bias and may not rely on ex post reasoning. *KSR*, 127 S.Ct. at 1742. In addition, evidence that such a combination was uniquely challenging or difficult tends to show that a claim was not obvious. *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. and Mattel, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007), citing *KSR*, 127 S.Ct. at 1741.

Applicant submits that even if *Marshall*, *Cohen*, and *Sorrell* could be properly combined (which Applicant disagrees), they would fail to teach all elements of Applicant’s amended claims. For example, amended Claim 11 recites:

11. A method of dispersing living cells comprising:
  - forming a suspension including a subject’s isolated autologous stem cells in a soluble medium;
  - placing the suspension into a receptacle of an air-jet sprayer having a nozzle orifice with a pore size of at least 1000 microns; and
  - dispersing the suspension onto a wound area of skin of the subject using the nozzle orifice of the air-jet sprayer;
  - wherein the forming the suspension and dispersing steps occur after, but within one day of the formation of the wound area.

*Marshall*, *Cohen*, and *Sorrell* do not teach dispersing a suspension of isolated autologous stem cells in a soluble medium using “an air-jet sprayer having a nozzle orifice with a pore size of at least 1000 microns.” The Examiner alleges that *Marshall*, column 7-8 teaches dispensing a solution of cells using an air-jet sprayer. (Office Action, page 8) However, *Marshall* explicitly teaches away from using a sprayer having a nozzle orifice with a pore size of at least 1000 microns. *Marshall* teaches the use of multi-lumen spray devices having “lumen diameters typically of 300  $\mu$ m or less.” (col. 8, line 14). Using a large orifice (1000 microns or larger) as claimed by Applicant is advantageous over prior art such as *Marshall* because it allows for a faster application of cells to the wound area, and allows for a desired flow rate to be achieved using a lower pressure, which reduces cell damage as compared with the smaller orifice, higher pressure technique of *Marshall*. In addition, as explained in Applicant’s specification at page 19, lines 5-8, using a larger nozzle orifice helps

overcome the problems of drying droplets and nozzle clogging. *Marshall* discussed this exact problem of drying droplets at col. 7, lines 52-61. However, *Marshall*'s solution to this problem was to control the timing of the mixing of the cell solution -- specifically, *Marshall* attempted to solve the problem of drying droplets by requiring that "mixing should occur immediately before, during or immediately after spraying." (col. 7, lines 53-55). Thus, the solution of using a large nozzle orifice was clearly not obvious to *Marshall*.

Further, *Marshall*, *Cohen*, and *Sorrell* do not teach "wherein the forming the suspension and dispersing steps occur after, but within one day of the formation of the wound area." In particular, in *Marshall*, the suspension the formation and dispersing steps were not performed until 10 days after the wound formation. (col. 12, lines 10-59). *Marshall* achieved results the authors considered satisfactory even with this delay; therefore, there is no teaching or suggestion to administer cells to a wound in any less time than 10 days. *Cohen* and *Sorrell* also fail to teach or suggest that forming a suspension of cells and dispersing the suspension on a wound area within one day of the formation of the wound area. The Examiner alleges that "it would be obvious to an artisan of ordinary skill in the clinical art to prepare and disperse the suspension containing living cells onto the desired area of skin wound (i.e. using a freshly prepared cell suspension in order to obtain the benefits of better wound healing properties of cells), and at the earliest possible time frame to avoid reduction in the beneficial activity of cells." The Examiner provides no evidence for this conclusory assertion. Applicant respectfully request that the Examiner either provide some reference or other evidence of preparing and dispersing a suspension containing living cells onto a wound area *within one day of the wound formation*. Applicant submits that if the Examiner is unable to find such evidence, the Examiner should thus acknowledge the novelty of this feature.

For at least the reasons above, Applicant respectfully requests reconsideration and allowance of amended Claim 11, as well as all claims that depend from Claim 11.

**Request for Continued Examination**

Applicant respectfully submits a Request for Continued Examination (RCE) Transmittal. The Commissioner is authorized to charge any fees required to Deposit Account 50-4871 in order to effectuate these filings.

**Association of Customer Number and Change of Correspondence Address**

Applicant respectfully requests that all papers pertaining to the above-captioned patent application be associated with Customer No. **86528**, and direct all correspondence pertaining to this patent application to practitioners at Customer Number **86528**. All telephone calls should be directed to Eric M. Grabski at 512.457.2030. A Revocation and Power of Attorney will be filed shortly.

**CONCLUSION**

Applicant has made an earnest effort to place this case in condition for allowance in light of the remarks set forth above. Applicant respectfully requests reconsideration of the pending claims.

Applicant encloses a Request for Continued Examination (RCE) and authorize the Commissioner to charge \$405.00 (RCE fee) to Deposit Account No. 50-4871 of King & Spalding LLP.

Applicant respectfully submits a Petition for Three-Month Extension of Time. The Commissioner is authorized to charge the fee of \$555.00 required to Deposit Account 50-4871 of King & Spalding LLP in order to effectuate this filing.

Applicant believes there are no additional fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 50-4871 of King & Spalding L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicant's attorney at 512.457.2030.

Respectfully submitted,  
KING & SPALDING L.L.P.  
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Date: July 13, 2009

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